



# UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO.            | FILING DATE                   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
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| 09/762,223                 | 05/07/2001                    | Antony Walter Anson  | 78014.018               | 2854             |
| 75                         | 590 09/25/2002                |                      |                         |                  |
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|                            |                               |                      | ART UNIT                | PAPER NUMBER     |
|                            |                               |                      | 3731                    |                  |
|                            |                               |                      | DATE MAILED: 09/25/2002 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary    Examiner   | •   |  | Application No.  | Applicant(s) |  |  |  |
|---|---|--|--|--------------|--|--|--|
| Paul A Roberts 3731  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Editations of them they be suitable under the provisions of 37 CFR 1.13(a). In no event, however, may a reply be timely filed after SIX (i) MONTH'S from the mailing able of this communication.  Fillums to reply within the set or extended period for reply well, by statute, cause the application to become ABANDONED (39 U.S.C. § 133). Any reply received by the Office able than three moments after the mailing date of this communication, even if timely filed, may reduce any statuted premote the statute application to become ABANDONED (39 U.S.C. § 133). Any reply received by the Office also than the trans disjustment. See 37 CFR 1.78(b).  Status  1)   |   |  | 09/762,223   | ANSON ET AL. |  |  |  |
| - The MALLING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13(a). In no event, however, may a reply be sinely fled after SN (6) MONTH'S from the mailing date of this communication.  If the period to reply specifical dove is less than three may (5) days, a reply within the statutory minimum of thinty (30) days, will be considered timely.  - Failure to reply within the set or extended period for reply with period will apply and will expire SN (6) MONTH'S from the mailing date of this communication.  - Failure to reply within the set or extended period for reply with period will apply and will expire SN (6) MONTH'S from the mailing date of this communication, even if timely flied, may reduce any examed patent term adjustment. See 37 CFR 1.704(b).  Status  - In this action is FINAL.  - In this action is FINAL.  - In this action is final to the mailing date of this communication, even if timely flied, may reduce any examed patent term adjustment. See 37 CFR 1.704(b).  This action is FINAL.  - In this action is final to the mailing date of this communication, even if timely flied, may reduce any examed patent term adjustment. See 37 CFR 1.704(b).  Status  - In this action is FINAL.  - In this action is final the mailing date of this communication.  - In this action is FINAL.  - In this action is final thin and the mailing date of this communication.  - In this action is FINAL.  - In this action is final thin and this action is non-final.  - In this action is final thin and this action is non-final.  - In this action is FINAL.  - In this action is final thin and this action is non-final.  - In this action is final thin and this action is non-final.  - In this action is action is action.  - In this action is final thin and this action is non-final.  - In this action is action |   |  | Examiner   | Art Unit     |  |  |  |
| A SHORTHEAD STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Elementors of time may be available under the provisions of 37 CFR 1.35(a). In no event, however, may a reply be timely filed  Elementors of time may be available under the provisions of 37 CFR 1.35(a). In no event, however, may a reply be timely filed  Elementors of time may be available under the provisions of 37 CFR 1.13(b). In no event, however, may a reply be timely filed  Elementors of time may be available under the provisions of 37 CFR 1.13(b). In no event, however, may a reply be timely filed  If the product or reply specified above, the maximum statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication. Feature to reply with the state cause the application become ARADONDED (59 U.S. 5, 133).  Status  1) Responsive to communication(s) filed on  |   |  |  |              |  |  |  |
| THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be variable under the provisions of 37 CFR 1.13(a). In no event, however, may a reply be timely filed after SIX (9) MONTH'S from the mailing date of this communication.  If the period or reply weithin the set or extended above is less share thing (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  Failure to reply weithin the set or extended period for reply within the statutory minimum of thirty (30) days will be considered timely.  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any samed patent term adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filed on  | Period for F  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply |  |              |  |  |  |
| 2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 51-70 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1 Certified copies of the priority documents have been received in Application No  3 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   | THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |  |              |  |  |  |
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| 4a) Of the above claim(s) is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) □ Claim(s) <u>51-69</u> is/are rejected.  7) □ Claim(s) <u>70</u> is/are objected to.  8) □ Claim(s) <u>70</u> is/are objected to.  8) □ Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) □ The specification is objected to by the Examiner.  10) □ The drawing(s) filed on <u>5/07/2001</u> is/are: a) □ accepted or b) □ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) □ The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) □ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All b) □ Some * c) □ None of:  1. □ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |              |  |  |  |
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| Priority under 35 U.S.C. §§ 119 and 120  13)  |   |  |  |              |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All b) □ Some * c) □ None of:  1. □ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |              |  |  |  |
| <ul> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   | Priority under 35 U.S.C. §§ 119 and 120   |  |  |              |  |  |  |
| <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> * See the attached detailed Office action for a list of the certified copies not received.  | 13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |  |  |              |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   | •   |  |  |              |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   | 1.[   | Certified copies of the priority documents   | have been received.                                    |              |  |  |  |
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|   | application from the International Bureau (PCT Rule 17.2(a)).   |  |  |              |  |  |  |
|   |   |  |  |              |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |  |  |              |  |  |  |
| Attachment(s)   |   |  |  |              |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9,10,11 5) Notice of Informal Patent Application (PTO-152) 6) Other:  |   |  |  |              |  |  |  |

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#### **DETAILED ACTION**

### **Drawings**

- 1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 1<sup>st</sup> and 2<sup>nd</sup> part, locating member, supporting member, and elongated member must be shown and labeled or the feature(s) canceled from the claim(s). No new matter should be entered.
- 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

## Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 51-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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- 6. In order to enable one of ordinary skilled in the art to build this invention, all objects in which the claims refer must be clearly described in the specification and drawn in the figures.
- 7. In claims 51-61 the applicant failed to label or describe to what the 1<sup>st</sup> and 2<sup>nd</sup> parts refer.
- 8. In claim 62 the applicant failed to label or describe to what the locating member and supporting member refer.
- 9. Claims 63-66 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The description of the elongate members is critical to the practice of the invention, but not included in the claim(s) and not enabled by the specification or drawings.

# Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 11. Claims 55 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 12. In claim 55, the applicant states "...parts are so sharpened." The phrase "so" requires a depending clause to change the normal intrinsic state of the noun being modified. For example, "... so sharpened as to allow them to puncture an artery." As written the claim is indefinite and is therefore rejected under 35 USC 112 second paragraph. An exception to this rule is when the word being modified has different levels in which it can be modified, like "the desk was so big." The use of the modifier for words like, "free, sharpened, full" is illogical and renders the claim indefinite.

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13. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

14. The applicant describes a helical structure in part C, yet there is no mention of a helical structure in the specification and no support in the diagrams to substantiate the claimed subject matter.

## Claim Rejections - 35 USC § 103

- 15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 16. Claim 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green, 6190401.
- 17. Regarding claim 68, the elongate member of the Green device has the capability of being in an open configuration, figure 14, and a retaining configuration, figure 1, where in the 1<sup>st</sup> and 2<sup>nd</sup> parts are closely spaced, wherein the device is biased towards the closed configuration. Further, the elongate member extends between the first and second element and is connected between the first and second ends. The modified Green device could be inserted into a graft-bearing artery to pierce the graft and artery. Once the device, part 1, is completely pushed through the artery, the graft and artery would be maintained between the first and second part where in the device would be in the closed position.

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18. Regarding claim 69, the fixator has 2 parts that are sharpened, allowing it to pierce an artery and a graft (see figure 14).

Figure 10

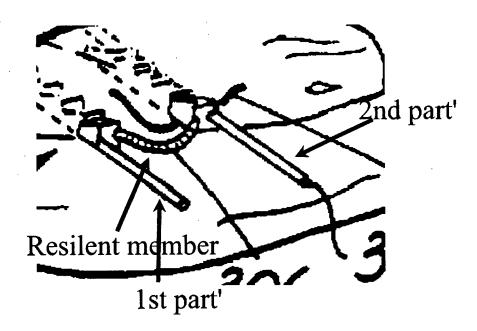
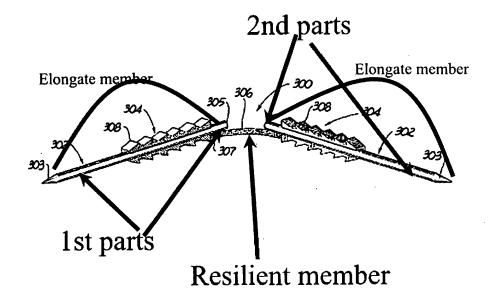


Figure 14



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### Allowable Subject Matter

- 19. Claim70 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 20. The following is an examiner's statement of reasons for allowance: The prior art does not teach a fixator with the limitations of claim 68 and biasing element.
- 21. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| 6071292 | The device has a very similar structure to the second embodiment of the |  |
|---------|---|--|
|         | invention.  |  |
| 5540716 | A surgical fastener   |  |
| 5984949 | A surgical fastener   |  |
| 5263973 | Surgical stapling method and apparatus                                  |  |

Plastic surgical staple

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts September 17, 2002

> MICHAEL J. MILANO SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

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